IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

MARILYN ARMSTRONG, et al.,

Plaintiffs,

v. CIVIL ACTION NO. 2:13-cv-24784

BOSTON SCIENTIFIC CORPORATION,

Defendant.

MEMORANDUM OPINION AND ORDER
(*Daubert* Motions)

Pending before the court are several *Daubert* motions filed by both the defendant and the plaintiffs. Briefing is complete regarding these motions, and the motions are now ripe for consideration.

I. Background

This case resides in one of seven Multidistrict Litigations ("MDLs") assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the six remaining active MDLs, there are more than 10,000 cases currently pending, approximately 2500 of which are in the Boston Scientific Corporation ("BSC") MDL, MDL No. 2326. The parties have disclosed experts to render opinions regarding the elements of the case's various causes of action, and the

instant motions involve the parties' efforts to exclude or limit the experts' opinions pursuant to *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if it will "help the trier of fact to understand the evidence or to determine a fact in issue" and (1) is "based upon sufficient facts or data" and (2) is "the product of reliable principles and methods," which (3) has been reliably applied "to the facts of the case." Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert*, 509 U.S. at 597. The proponent of expert testimony does not have the burden to "prove" anything. However, he or she must "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court's role as gatekeeper is an important one. "[E]xpert witnesses have the potential to be both powerful and quite misleading"; the court must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 588, 595; *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)). I "need not determine that the proffered expert testimony is irrefutable or certainly correct. As with all other admissible evidence, expert testimony is subject to testing by '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *United States v. Moreland*, 437 F.3d 424, 431

(4th Cir. 2006) (alteration in original) (citation omitted) (quoting *Daubert*, 509 U.S. at 596); *see also Md. Cas. Co.*, 137 F.3d at 783 ("All *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful.").

Daubert mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94).

Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("We agree with the Solicitor General that '[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.'" (alteration in original)); *see also Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").

With respect to relevancy, *Daubert* also explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of "fit." "Fit" is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's "helpfulness" standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591-92 (citations and internal quotation marks omitted).

Ultimately, the district court has broad discretion in determining whether to admit or exclude expert testimony, and the "the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Cooper*, 259 F.3d at 200 (quoting *Kumho Tire*, 526 U.S. at 152).

III. Preliminary Matter

I begin by addressing a preliminary matter that affects many of the *Daubert* motions. Both parties consistently challenge experts' opinions as improper state-of-mind or legal-conclusion testimony. As I have maintained throughout these MDLs, I will not permit the use of experts to usurp the jury's fact-finding function by allowing an expert to testify as to a party's knowledge, state of mind, or whether a party acted reasonably. *See, e.g.*, *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013) (excluding expert opinions on the defendant's knowledge, state of mind, alleged bad acts, failures to act, and corporate conduct and ethics). The reasonableness of conduct and a party's then-existing state of mind "are the sort of questions that lay jurors have been answering without expert assistance from time immemorial," and

therefore, these matters are not appropriate for expert testimony. *Kidder v. Peabody & Co. v. IAG Int'l Acceptance Grp., N.V.*, 14 F. Supp. 2d 391, 404 (S.D.N.Y. 1998); *see also In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) ("Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony.").[1] Likewise, "opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible." *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006). An expert may not state his opinion using "legal terms of art," such as "defective," "unreasonably dangerous," or "proximate cause." *See Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).

I have diligently applied these rules to previous expert testimony, and I continue to apply them in this case. This does not mean that each objection to state-of-mind or legal-conclusion testimony raised in these motions is valid. But I will not parse the numerous reports and thousand-page depositions for each expert to determine the validity of these same objections. Instead, the onus is on counsel to tailor expert testimony at trial in accordance with the above directive. Therefore, unless otherwise necessary, the remainder of this opinion does not address objections brought against an expert based on improper state-of-mind or legal-conclusion testimony.

[1] On a related note, I caution the parties against introducing corporate evidence through expert witnesses. Although an expert may testify about his review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions—assuming the opinions are otherwise admissible—he or she may not be offered solely as a conduit for corporate information. There is no reason why the plaintiffs require an expert to opine on such facts.

IV. BSC's *Daubert* Motions

BSC seeks to limit or exclude the testimony and opinions of Drs. Peggy Pence, Scott Guelcher, Vladimir Iakovlev, and Richard Bercik.

A. Dr. Peggy Pence, Ph.D., RAC, FRAPS

Dr. Peggy Pence is a clinical and regulatory consultant who provides advice, guidance, and product development services to pharmaceutical/biopharmaceutical and medical device companies in the areas of strategic planning, preclinical testing, clinical trials, design and conduct, and regulatory matters involving the FDA.

1. Qualifications

BSC maintains that Dr. Pence's work as a researcher and consultant on the development of medical products does not qualify her to opine about the safety and efficacy of mesh products, as she attempts to do in her expert report. Dr. Pence has over forty years of experience in the research and development of medical devices. Over that time, she has accumulated knowledge that is relevant to this case, such as the design of clinical trials for diseases of the female genital system, the clinical testing of novel medical devices, and the content of product labeling. Accordingly, I **FIND** that Dr. Pence is qualified to render the opinions set forth in her expert report.

2. General Objections

I begin by addressing two objections that BSC raises multiple times throughout its motion, all related to the reliability of the authoritative sources underlying Dr. Pence's opinions, which include a 2006 study by the French National Authority for Health ("HAS"), the recommendations of the National Institute for

Health and Care Excellence ("NICE"), and the various guidance documents drafted by the Global Harmonization Task Force ("GHTF").[2] BSC has not cited any case suggesting that the binding effect of industry standards dictates their reliability. Indeed, the Seventh Circuit Court of Appeals has suggested the opposite:

> [T]he relevant question for admissibility purposes is not whether the . . . guidelines are controlling in the sense of an industry code, or even how persuasive they are. It is only whether consulting them is a methodologically sound practice on which to base an expert opinion in the context of this case.

Lees v. Carthage Coll., 714 F.3d 516, 525 (7th Cir. 2013). Accordingly, I give no import to the nonbinding nature of the HAS, NICE, and GHTF recommendations in my *Daubert* analysis and instead focus on whether Dr. Pence's reliance on these sources constitutes a methodologically sound practice.

BSC also attempts to equate GHTF standards with FDA regulations and asserts that, like FDA regulations, admission of GHTF standards, which have "regulatory purpose, history, and focus," could confuse and mislead the jury. GHTF standards do not carry the same prejudicial force—the government does not promulgate them, manufacturers are not bound by them, and jurors are not familiar with them. Although the FDA appears to have had a limited role in the activities of the GHTF, that role was not instrumental or definitive, and the work of the GHTF

[2] The GHTF, which was conceived in 1992 and replaced by the International Medical Device Regulators Forum ("IMDRF") in 2011, represented a partnership between regulatory authorities and regulated industry and sought to achieve greater uniformity between national medical device regulatory systems. The European Union, United States, Canada, Australia, and Japan were the founding members, and these entities, as well as Brazil, China, Japan, and Russia, currently form the Management Committee of the IMDRF. Dr. Pence relies on several GHTF "Final Documents" in reaching her opinions.

can be described without reference to the FDA. Accordingly, I **FIND** BSC's argument without merit.

3. Premarket Testing

Generally, BSC contends that none of the studies Dr. Pence relies on support her opinion that BSC should have performed premarket clinical trials. My review of the exhibits, however, indicates that several guidance documents supply a basis for this opinion. Additionally, although the NICE and HAS studies are not as explicit as the GHTF documents, they both emphasize the importance of clinical trials in assessing a product's safety for surgical use. Furthermore, all of these documents carry the indicia of reliability set forth by *Daubert*: the conclusions were reached after documented and validated testing, the results were published, and the testing was conducted through a defined methodology described in each paper. Therefore, I **FIND** Dr. Pence's consultation of these sources in reaching her opinion both justified and reliable.

Next, BSC argues that Dr. Pence's report lacks a discussion of the GHTF standard itself and how Dr. Pence's application of that standard led her to form the opinions contained in her report. These remaining arguments go to the weight of Dr. Pence's testimony, not its reliability, and are therefore better suited for cross-examination. In conclusion, I **DENY** BSC's Motion to exclude Dr. Pence's opinion on premarket clinical testing.

4. Product Labels

BSC asserts that to the extent Dr. Pence's opinions on product labeling relate to BSC's deviation from the branding requirements of the Food, Drug, and Cosmetic Act ("FDCA"), they should be excluded. I agree. As I have held several times in the course of these MDLs, expert testimony about the requirements of the FDCA, which are not at issue in this case, could lead to more confusion about the state tort claims than enlightenment. I cannot admit Dr. Pence's testimony as it relates to the FDCA or FDA regulations. *See Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 755 (S.D. W. Va. 2014) (agreeing that "alleged shortcomings in FDA procedures are not probative to a state law products liability claim"). These opinions are **EXCLUDED**.

This finding, however, does not result in the exclusion of Dr. Pence's opinion on product labeling altogether because, unlike in previous cases, Dr. Pence has a second source of information that is unrelated to the FDA (i.e., the GHTF's *Label and Instructions for Use for Medical Devices*), which I must also consider in my analysis. The GHTF document on product labels does not state—expressly or otherwise—that manufacturers should include the severity, frequency, and permanency of adverse events in a warning, nor does it state that a label should qualify the difficulty of removing the device. Furthermore, Dr. Pence does not explain how this document could be interpreted as such. Seeing no non-FDA grounds for Dr. Pence's opinion that BSC should have included this particular information in its labels, I **FIND** it unreliable, and it is therefore **EXCLUDED**.[3]

[3] BSC raises this objection only to Dr. Pence's opinions that the label should have included information on the difficulty of mesh removal and the permanency, severity, and frequency of adverse events. My

With respect to Dr. Pence's remaining opinions on product labeling, BSC moves for exclusion because Dr. Pence never spoke to any physicians about this issue. An expert's failure to examine a particular source of information is not grounds for exclusion under *Daubert* so long as the expert has other "sufficient facts or data" to support her opinion. Fed. R. Evid. 702. Here, Dr. Pence considered the GHTF's *Label and Instructions for Use for Medical Devices*, the DFU, several BSC internal documents, and other medical and scientific literature. I find this collection of sources sufficient for the purposes of *Daubert*. BSC has ample grounds to cross-examine and impeach Dr. Pence at trial regarding any perceived oversights in her analysis.

5. Post-Market Vigilance

In arriving at her post-market vigilance opinions, Dr. Pence exclusively considered data from the FDA's MAUDE database.[4] As I have previously explained, BSC's communication, or alleged lack thereof, with the FDA through the MAUDE database has "no bearing on whether BSC provided adequate warnings or whether its products were defective." *Sanchez*, 2014 WL 4851989, at *36. Any opinion based on data collected in the MAUDE database, which acts as an arm of the FDA, is not helpful to the jury and is therefore inadmissible. *See* Fed. R. Evid. 702 (stating that the expert's specialized knowledge must "help the trier of fact to understand the

holding is therefore limited to these specific opinions as well.

[4] "The MAUDE database houses medical device reports submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers." FDA, *MAUDE—Manufacturer and User Facility Device Experience*, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Search.cfm (last visited April 3, 2016).

evidence or to determine a fact in issue"). Because Dr. Pence's opinion on post-market vigilance appears to be entirely based on data—or lack thereof—found in the MAUDE database, I find it unreliable. Without a reliable basis, Dr. Pence's opinion on BSC's inadequate post-market vigilance is **EXCLUDED**, and BSC's Motion on this matter is **GRANTED**.

6. Carcinogenicity of Polypropylene

Finally, BSC argues that Dr. Pence's opinions regarding the carcinogenicity of polypropylene mesh must be excluded as unreliable, irrelevant, and prejudicial. The plaintiff does not contest this argument. Therefore, BSC's Motion on this point is **GRANTED**.

7. Final Caveat: Relevance

BSC argues that several of the standards Dr. Pence relies on were not published until after the device at issue was marketed, making those standards irrelevant to this case. I **RESERVE** ruling on this matter until trial.

In sum, BSC's Motion to Exclude the Opinions and Testimony of Peggy Pence, Ph.D. [ECF No. 48] is **GRANTED in part, DENIED in part**, and **RESERVED in part**.

B. Dr. Scott Guelcher, Ph.D.

Dr. Scott Guelcher is a chemical engineer offered by the plaintiffs to opine on how the human body responds to polypropylene once it is implanted and the reactions that occur on the surface of the implant. Dr. Guelcher's opinions—to the extent they are based on Dr. Dunn's testing—are **EXCLUDED** because Dr. Dunn's testing is unreliable. Dr. Dunn's *in vitro* testing failed to follow the written protocol he relied

upon in developing his test—the very protocol that Dr. Guelcher developed. Specifically, Dr. Dunn could not account for why he changed the testing solution once a week when the protocol called for changing the solution once every three days. Further, Dr. Dunn stated in his deposition that he would only use his testing to show the general behavior of polypropylene mesh in an *in vitro* oxidizing medium—not to extend what that means inside the body. Dr. Dunn's testing lacks sufficient indicia of reliability. Therefore, BSC's Motion to Exclude the Opinions and Testimony of Scott Guelcher, Ph.D. [ECF No. 51] is **GRANTED**.

C. Dr. Vladimir Iakovlev, M.D.

Dr. Vladimir Iakovlev is an anatomical pathologist and the Director of Cytopathology as the Department of Laboratory Medicine at St. Michael's Hospital in Toronto, Canada.

1. General Causation

BSC contends that this court should exclude Dr. Iakovlev's opinions on specimens other than the plaintiff's. Dr. Iakovlev's general causation opinions are based largely on his examination of the mesh explant samples in his personal data pool. However, Dr. Iakovlev provides no information on how the mesh explants were chosen or prepared for examination. Dr. Iakovlev testified that plaintiffs' counsel provided approximately seventy percent of the transvaginal mesh explants, but he does not know how those explants were chosen or what methodology counsel employed.

Accordingly, BSC's motion on this matter is **GRANTED**, and Dr. Iakovlev's general causation opinions based on his data pool are **EXCLUDED**.

2. Specific Causation

It is unclear whether Dr. Iakovlev intends to offer a specific causation opinion in this case because the court has not been provided with an expert report from Dr. Iakovlev specific to this plaintiff. In this case, there is no evidence that Dr. Iakovlev examined the plaintiff's explanted mesh or performed a physical examination. Assuming Dr. Iakovlev seeks to offer specific causation opinions, such opinions are not sufficiently reliable under *Daubert* and are thus **EXCLUDED**.

In conclusion, BSC's Motion to Strike and Exclude the Opinions and Testimony of Vladimir Iakovlev, M.D. [ECF No. 56] is **GRANTED**.

D. Dr. Richard Bercik, M.D.

Dr. Richard Bercik is urogynecologist and surgeon with extensive experience using polypropylene mesh products.

1. Polypropylene Properties

BSC argues that Dr. Bercik is not qualified to offer opinions regarding stiffness, porosity, bridging fibrosis, scar-plate formation, or degradation because Dr. Bercik is not a biomaterials expert. Dr. Bercik has performed over 2000 surgeries implanting POP and SUI mesh devices, and he has performed over 250 surgeries removing pelvic floor synthetic mesh. The plaintiff concedes that Dr. Bercik will not be asked to provide chemical explanations regarding stiffness, porosity, etc. Instead, the plaintiff states that Dr. Bercik's opinions will not go beyond reporting the clinical

effects Dr. Bercik has seen in his practice and review of the scientific literature. I **FIND** that Dr. Bercik is qualified to discuss these matters as it relates to his clinical experience. BSC's Motion is **DENIED** on this point.

2. Labeling Opinions

Next, BSC argues that Dr. Bercik's opinions on the adequacy of its Directions For Use ("DFU") should be excluded because they were not disclosed in his expert report and because he is unqualified to offer them. In response, the plaintiffs note that Dr. Bercik only offered his opinions on the DFU during his deposition in response to a question by BSC's counsel, and concede that Dr. Bercik will not offer this opinion at trial. Therefore, BSC's Motion on this point is **DENIED as moot**.

3. Degradation

BSC next argues that Dr. Bercik's opinion that polypropylene degradation has occurred in the plaintiff is not helpful to a jury because Dr. Bercik did not personally examine the plaintiff's mesh explant, but instead relied on a pathology report from another expert. Rule 703 of the Federal Rules of Evidence states, "An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed. If experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need to be admissible for the opinion to be admitted." I **FIND** that Dr. Bercik may reasonably rely on expert pathology reports to assist him in forming his opinion. BSC's Motion on this point is **DENIED**.

4. Specific Causation

BSC argues that Dr. Bercik's specific causation opinions should be excluded as unreliable; however, BSC raises concerns for opinions relating to four plaintiffs—none of whom is the plaintiff in this case. Accordingly, BSC's Motion is **DENIED** on this point.

In sum, BSC's Motion to Exclude the Testimony of Dr. Bercik, M.D. [ECF No. 49] is **DENIED in part** and **DENIED as moot in part.**

V. The Plaintiffs' *Daubert* Motions

The plaintiffs seek to limit or exclude the testimony and opinions of Drs. Christine Brauer, Stephen Spiegelberg, Stephen F. Badylak, and Lonny Green.

A. Dr. Christine Brauer, Ph.D.

Dr. Christine Brauer is the President of Brauer Device Consultants LLC, where she provides consulting services to the medical device industry regarding FDA regulatory requirements.

The plaintiffs seek to exclude both of Dr. Brauer's expert reports filed on November 21, 2014. The first report ("FDA report") focuses on the FDA regulatory framework for surgical devices, and the second report ("supplemental report") focuses on industry standards that a manufacturer of a medical device must meet. I have repeatedly and thoroughly considered the admissibility of the FDA's 510(k) process, and I have consistently found that the 510(k) process does not relate to safety or efficacy. Therefore, the parties may not present evidence regarding the 510(k) clearance process or subsequent FDA enforcement actions. Accordingly, the plaintiffs'

Motion with regard to Dr. Brauer's FDA report is **GRANTED**, and her opinions set forth in that report are **EXCLUDED**.

With regard to the supplemental report, the plaintiffs contend that it is nothing more than her FDA report under a different cloak. I agree. Reading the two reports side by side, it appears that Dr. Brauer "supplemented" her report by removing references to the FDA and substituting the term "industry standard" instead. This "industry standard" clearly describes the FDA 510(k) process, which Dr. Brauer admits in her deposition. There is far too much overlap between Dr. Brauer's FDA report and supplemental report to avoid a regulatory mini-trial, which I have repeatedly and consistently held would confuse and mislead the jury. Accordingly, the plaintiffs' Motion to Exclude or Limit the Testimony of Christine Brauer, Ph.D. [ECF No. 43] is **GRANTED**, and Dr. Brauer's opinions are **EXCLUDED** in their entirety.

B. Dr. Stephen Spiegelberg, Ph.D.

Dr. Stephen Spiegelberg is the president and co-founder of Cambridge Polymer Group Inc., where he directs a team of scientists who perform contract research, analytical testing, and device development for the biomedical and polymer industries.

1. Position Statements

First, the plaintiffs argue that Dr. Spiegelberg's opinions regarding position statements should be excluded because (1) they are not contained in his expert report; (2) he is not qualified to offer such opinions; and (3) he lacks any reliable methodology. Upon review, I agree with BSC that Dr. Spiegelberg does not in fact offer the opinions

the plaintiffs seek to exclude. Accordingly, the plaintiffs' Motion with regard to position statements is **DENIED as moot**.

2. FDA

Next, the plaintiffs contend that Dr. Spiegelberg is unqualified to opine on the FDA 510(k) clearance process and that such opinions should be excluded as irrelevant. In response, BSC concedes that Dr. Spiegelberg will not offer opinions on the FDA 510(k) clearance process. Accordingly, the plaintiffs' Motion with regard to the FDA is **DENIED as moot.**

BSC limits its concession by arguing that Dr. Spiegelberg is qualified to opine on International Organization for Standardization ("ISO") standards based on his experience in the field of medical device analysis and design. I agree. Dr. Spiegelberg's current work revolves around medical device development and consultation. He is also the Task Force Chairman for the American Society for Testing and Materials ("ASTM"), which establishes standards involving the cleanliness of biomedical devices and characterization methods for polymers. Consulting on the development of new medical products requires familiarity with the applicable industry standards. Therefore, to the extent Dr. Spiegelberg intends to opine on ISO standards without referencing the FDA, I find him qualified to do so. Accordingly, the plaintiffs' Motion with regard to Dr. Spiegelberg's qualifications is **DENIED**.

3. Black Specks or Spots

Next, the plaintiffs argue that Dr. Spiegelberg's opinions regarding black specks in BSC's mesh are unfounded and unreliable. In his expert report, Dr.

Spiegelberg states that the "black spots" are actually reflections of light on the curves of the mesh when pictures are taken, rather than inclusions or defects in the mesh. The plaintiffs contend that Dr. Spiegelberg's findings are unreliable because he did not review the photographs supplied by a plaintiff's expert, Dr. Dunn, nor did he take his own photographs. Whether Dr. Spiegelberg took his own photographs does not sufficiently undermine the reliability of his analysis here. Challenges to Dr. Spiegelberg's ultimate conclusion with regard to the nature of the black spots are better suited for cross-examination. Accordingly, the plaintiffs' Motion with regard to black specks or spots is **DENIED**.

4. **FTIR and EDS**

Finally, the plaintiffs seek to limit Dr. Spiegelberg's general causation opinions based on his Fourier Transform Infrared Spectroscopy ("FTIR") and Electron Dispersive Spectroscopy ("EDS") testing. However, the plaintiff points out that Dr. Spiegelberg's admissions regarding the limitations of these testings may also be grounds for cross-examination and thus seeks only qualification or explanation of the limitations inherent to the testing in order to avoid misleading or confusing the jury. The plaintiffs will have the opportunity to adequately highlight these limitations at trial upon cross-examination. Accordingly, the plaintiffs' Motion with regard to Dr. Spiegelberg's FTIR and EDS testing is **DENIED**.

In sum, the plaintiffs' Motion to Exclude the Testimony and Opinions of Dr. Stephen Spiegelberg, Ph.D. [ECF No. 54] is **DENIED in part** and **DENIED as moot in part**.

C. Dr. Stephen F. Badylak, D.V.M., Ph.D., M.D.

Dr. Stephen Badylak is the Deputy Director of the McGowan Institute for Regenerative Medicine, Director of the Center for Preclinical Studies, and a tenured professor with the Department of Surgery at the University of Pittsburgh.

1. Risk-Benefit Analysis or Safety and Efficacy

The plaintiffs contend that Dr. Badylak should be precluded from opining on the safety and efficacy of polypropylene mesh devices because he has not reviewed the applicable scientific literature and he has no clinical experience using these devices. Dr. Badylak's expert report indicates that he reviewed more than 200 relevant scientific publications, including more than twenty publications evaluating the safety and efficacy of BSC devices. Furthermore, Dr. Badylak explains that he is more familiar with the body of literature reviewing the safety and efficacy of surgical mesh generally, versus literature specific to any one device. This explanation does not undermine his qualifications but instead clarifies his approach. If there are certain device-specific publications that Dr. Badylak failed to review in preparing his expert report, the plaintiffs are free to ask him about those publications on cross-examination.

Similarly, the plaintiffs' arguments regarding Dr. Badylak's clinical experience are also without merit. Dr. Badylak has extensive experience in the field of biomaterials, including the design of implantable surgical mesh devices. Accordingly, the plaintiffs' Motion with regard to Dr. Badylak's safety and efficacy opinions is **DENIED**.

2. Lack of Correlation Between Microscopic Findings of Explanted Mesh and Clinical Symptoms

Next, the plaintiff seeks to exclude Dr. Badylak's opinions noting a lack of correlation between microscopic findings of explanted mesh with clinical symptoms such as dyspareunia. I **FIND** that Dr. Badylak's opinions on this point are based on a reliable methodology. If the plaintiffs feel that Dr. Badylak failed to consider certain literature to the contrary, they can address this purported shortcoming on cross-examination. The plaintiffs' Motion on this point is **DENIED**.

3. Degradation

Finally, the plaintiffs argue that Dr. Badylak's opinions with regard to oxidative degradation based on the scientific literature are unreliable because he contradicted himself during his deposition by acknowledging the "phenomenon" of oxidative reactions. However, the plaintiffs omit Dr. Badylak's subsequent testimony, where he states that he does not believe that oxidative reactions at the surface of polypropylene results in the degradation that causes further problems. Upon review of the deposition, I do not find Dr. Badylak's testimony sufficiently contradictory to undermine the reliability of his expert opinions. Accordingly, the plaintiffs' Motion with regard to degradation is **DENIED**.

The plaintiffs' Motion to Exclude the Opinions and Testimony of Stephen F. Badylak, D.V.M., Ph.D., M.D. [ECF No. 55] is thus **DENIED**.

D. Dr. Lonny Green, M.D.

Dr. Lonny Green is a board-certified urologist whose practice is largely focused on the treatment of female urinary incontinence and who has extensive experience

with the Obtryx. Dr. Green opines that mid-urethral slings, like the Obtryx, are the standard of care in the treatment of SUI.

1. Adequacy of Warnings

First, the plaintiffs argue that Dr. Green is not qualified to offer opinions on the Obtryx DFU because he has never written a DFU and could not describe the general requirements for a DFU during his deposition.

In the past, I allowed a doctor to testify that the DFU was inadequate because it failed to warn against risks the doctor observed in his or her own practice. In contrast, now I must determine whether the same kind of doctor is instead qualified to offer his expert opinion that the warnings were in fact adequate. There is a clear distinction. The plaintiffs' experts observed certain risks and complications in their practice and then sought to opine that those risks should have been included in the product warnings. In the present case, BSC's experts have observed certain risks and complications in their practice, which are warned of in the DFU, and therefore deduce that there are no other possible risks or complications that should have been included. The plaintiffs' experts address a discrete risk which they have personally observed, while BSC's experts' opinions attempt to encompass all possible risks, none of which they have personally observed. Accordingly, I **FIND** that without additional expertise in the specific area of product warnings, a doctor, such as a urologist or urogynecologist, is not qualified to opine that a product warning was adequate, merely because it included risks he has observed in his own practice.

Dr. Green fails to address the significance of complications he has not seen in his practice, and which are not warned of in the DFU. In his deposition, Dr. Green admits he has never drafted a DFU for a medical device or pharmaceutical. Although Dr. Green indicates he has "expertise" in the process of writing patient handouts warning against drug complications, his experience appears to be limited to his review and distribution of these handouts, rather than contribution to the drafting. Accordingly, I **FIND** that Dr. Green is not qualified to opine on the adequacy of product warnings, and therefore, his opinions related to the Obtryx DFU are **EXCLUDED**.

2. FDA 510(k) Clearance

BSC concedes that Dr. Green will not offer opinions on the FDA 510(k) clearance process. Furthermore, I have repeatedly held that the probative value of FDA evidence is substantially outweighed by the risk of jury confusion. Therefore, to the extent Dr. Green seeks to offer other expert opinions on the FDA, such opinions are likewise **EXCLUDED**, and the plaintiffs' Motion is **GRANTED** on this point.

3. Physical Properties of Polypropylene

a. Qualifications

The plaintiffs argue that Dr. Green is not qualified to opine that the Obtryx does not shrink, contract, degrade, or cause systemic infections. I disagree. A lack of personal experience performing pathology research on polypropylene explants does not necessarily render Dr. Green unqualified under Rule 702 to offer opinions on the suitability of the Obtryx device.

Dr. Green has performed almost 3000 sling procedures, and his clinical practice has largely focused on the treatment of female urinary incontinence over the last twenty years. Further, Dr. Green cites numerous studies and academic papers throughout his expert report to support his opinion that the Obtryx is both safe and effective. I therefore **FIND** that Dr. Green is qualified to offer the opinion that the Obtryx mesh does not shrink, contract, degrade, or cause systemic infections. The plaintiffs' Motion is **DENIED** on this point.

b. Reliability

The plaintiffs challenge the reliability of Dr. Green's opinion on the physical properties of mesh—specifically that there is no evidence the device in question contracts, degrades, or causes systemic infection. Dr. Green claims he based this opinion on his clinical experience, during which he did not observe evidence of such mesh properties, and upon review of medical and scientific literature.

The advisory committee notes to Rule 702 state:

> If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts. The trial court's gatekeeping function requires more than simply "taking the expert's word for it."

Fed. R. Evid. 702 advisory committee's note to 2000 amendment (citing *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1995) ("We've been presented with only the expert's qualifications, their conclusions and their assurances of reliability. Under *Daubert*, that's not enough.")).

Yet the Fourth Circuit appears more willing to "take the expert's word for it" so long as the expert has demonstrated that he or she has experience in a field writ large. *See, e.g., Eskridge v. Pac. Cycle, Inc.*, 556 F. App'x 182, 190–91 (4th Cir. 2014) (unpublished) (finding a bicycle engineer's experience with "hundreds of cases of accidents" and "decades of experience in the industry in general" provided a reliable basis to testify about whether bicycle purchasers read warnings and dismissing concerns that the bicycle expert's testimony was nothing more than personal opinion because of his "years of experience" and assurance that all of his opinions were "to a reasonable degree of engineering certainty").

On the one hand, Dr. Green has based his opinions on his extensive clinical experience and a review of the medical and scientific literature, which, in the abstract, are reasonable bases from which to form an expert opinion. *See Kumho*, 526 U.S. at 156 ("[N]o one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience.").

On the other hand, the court does not have enough information to judge the reliability or relevance of these particular clinical observations—as distinguished from experience examining mesh explants. Perhaps Dr. Green did not observe evidence of mesh contraction because he was not looking. Or perhaps his method of identifying and tracking the complications at issue is not scientifically sound. Additionally, sweeping statements about support within the medical community or medical literature can be difficult to assess. Although the expert report indicates Dr. Green reviewed an extensive list of literature in forming his opinions generally, the

court is directed to minimal specific support for the statements at issue or detail about Dr. Green's methodology.

In this specific context, I am without sufficient information at this time to draw the fine line between reliable and unreliable expert testimony on physical mesh properties based primarily on a doctor's clinical observations, or lack thereof. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

For the above reasons, the plaintiffs' Motion to Exclude the Opinions and Testimony of Lonny Green, M.D. [ECF No. 44] is **GRANTED in part, DENIED in part** and **RESERVED in part**.

VI. Effect of *Daubert* Ruling

I emphasize that my rulings excluding expert opinions under Rule 702 and *Daubert* are dispositive of their potential admissibility in these cases, but my rulings not to exclude expert opinions are not dispositive of their admissibility at trial. In other words, to the extent that certain opinions might be cumulative or might confuse or mislead the jury, they may still be excluded under Rule 403 or some other evidentiary rule. I will take up these issues as they arise.

VII. Conclusion

For the reasons stated above, my rulings on BSC's *Daubert* motions are as follows: the Motion to Exclude the Opinions and Testimony of Peggy Pence, Ph.D. [ECF No. 48] is **GRANTED in part, DENIED in part**, and **RESERVED in part**; the Motion to Exclude the Opinions and Testimony of Scott Guelcher, Ph.D. [ECF No. 51]

is **GRANTED**; the Motion to Strike and Exclude the Opinions and Testimony of Vladimir Iakovlev, M.D. [ECF No. 56] is **GRANTED**; and the Motion to Exclude the Testimony of Dr. Bercik, M.D. [ECF No. 49] is **DENIED in part** and **DENIED as moot in part.**

For the reasons stated above, my rulings on the plaintiff's *Daubert* motions are as follows: the Motion to Exclude or Limit the Testimony of Christine Brauer, Ph.D. [ECF No. 43] is **GRANTED**; the Motion to Exclude the Testimony and Opinions of Dr. Stephen Spiegelberg, Ph.D. [ECF No. 54] is **DENIED in part** and **DENIED as moot in part**; the Motion to Exclude the Opinions and Testimony of Stephen F. Badylak, D.V.M., Ph.D., M.D. [ECF No. 55] is thus **DENIED**; and the Motion to Exclude the Opinions and Testimony of Lonny Green, M.D. [ECF No. 44] is **GRANTED in part, DENIED in part** and **RESERVED in part**.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: August 10, 2018

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE